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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/581,890 | 08/28/2000 | Oliver Brustle | V0S-012 | 7106 |

23483 7590 03/13/2006

WILMER CUTLER PICKERING HALE AND DORR LLP
60 STATE STREET
BOSTON, MA 02109

| EXAMINER | |
|---|---|
| FALK, ANNE MARIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Interview Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/581,890 | BRUSTLE, OLIVER | |
| | Examiner | Art Unit | |
| | Anne-Marie Falk, Ph.D. | 1632 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *Anne-Marie Falk, Ph.D.*.

(2) *Ann-Louise Kerner, Ph.D.*.

(3)*Alison E. Corkery*.

(4)*Oliver Brustle, Ph.D. & Martin Grund*.

Date of Interview: *07 March 2006*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *draft claims proposed in attached document*.

Identification of prior art discussed: *USPN 5,980,885 (Weiss et al.)*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

# Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

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The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

**Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Continuation Sheet (PTOL-413)**

**Substance of Interview:** Discussed the attached draft claims, particularly the new limitations presented in Claim 2 and where support can be found in the specification. Applicant argued that the cell composition disclosed on page 24, lines 31-38 comprises only neural precursor cells and neurons and that there is no overlap in expression of nestin and βIII-tubulin in the lineage from neural precursor cell to neuron. However, it was not evident that the O4-positive cells with oligodendroglial morphology, present as 6.2% of the composition, and the GFAP-positive astrocytes, present as 30% of the composition, were consistent with this interpretation. The Examiner advised Applicant that the disclosure at page 24 would constitute support only for the very specific cell composition disclosed in terms of percentage of neural precursor cells, neurons, astrocytes, and oligodendroglia, but the broader language recited in the claims of "no more than about 34% isolated neural cells" must be supported in the specification. Thus, the new limitations presented in Claim 2 may represent new matter unless specific support is found in the specification. Further discussed the rejection under 35 U.S.C. 102(e) citing USPN 5,980,885 (Weiss et al.). The Examiner advised Applicant that she would have to review the reference to determine if it would apply to the amended claims and further that a search of the prior art may turn up additional art that applies to the proposed claims.

WILMERHALE

FACSIMILE

+1 617 526 6517 (t)
+1 617 526 5000 (f)
alison.corkery@wilmerhale.com

Date March 7, 2006

To Anne Marie Falk
USPTO

Fax 571-273-0728
Tel

cc

From Alison E. Corkery

Pages 8 (including cover)

Re

Draft Claims for Interview.

# DRAFT CLAIMS

PATENTS
Atty. Docket No. VOS-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Applicant: | Oliver Bruestle | Art Unit: | 1632 |
| Serial No.: | 09/581,890 | Examiner: | Falk, Anne Marie |
| Filing Date: | August 28, 2000 | Conf. No.: | 7106 |
| Title: | **NEURAL PRECURSOR CELLS, METHOD FOR THE PRODUCTION AND USE THEREOF IN NEURAL DEFECT THERAPY** | Cust. No.: | 23483 |

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Cancelled)

2. (Currently Amended) A non-tumorigenic cell composition derived from **murine or human** embryonic stem cells, the composition comprising **cells consisting essentially of at least about 66% isolated neural precursor cells and no more than about 34% isolated neural cells**~~about 100% isolated neural cells and neural precursor cells~~, the neural precursor cells having the ability to differentiate into neuronal cells or glial cells,

the composition being obtainable by:

(a) culturing the embryonic stem cells to produce neural precursor cells;

(b) culturing the neural precursor cells from (a) in a first growth factor-containing serum-free medium;

# DRAFT CLAIMS

(c) culturing the cells from (b) in a second growth factor-containing serum-free medium; and

(d) culturing the cells from (c) in a third growth factor-containing serum-free medium,

wherein the cultured cells from (d) are non-tumorigenic and comprise neural cells and neural precursor cells,

wherein the neural precursor cells have the ability to differentiate into neuronal cells or glial cells, and

**wherein the embryonic stem cells are not human genetically modified embryonic stem cells.**

3. (Previously Presented) The cell composition according to claim 2, wherein the embryonic stem cells in step (a) are in the form of cell aggregates.

4. (Cancelled)

5. (Cancelled)

6. (Previously Presented) The cell composition according to claim 2, wherein the cells of steps (c) and (d) grow as a monolayer.

7. (Cancelled)

8. (Previously Presented) The cell composition according to claim 2, comprising cells with neuronal, astroglial or oligodendroglial properties.

9. (Previously Presented) The cell composition according to claim 2, wherein the embryonic stem cells are obtained after nuclear transfer into oocytes.

10. (Previously Presented) The cell composition according to claim 2, wherein the embryonic stem cells are obtained from embryonic germ cells.

# DRAFT CLAIMS

11. (Cancelled)

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15. (Previously Presented) A cell library comprising autologous and non-autologous cells according to claim 47.

16. – 45. (Cancelled)

46. (Previously Presented) A pharmaceutical composition comprising the precursor cells of claim 47.

47. (Currently Amended) A non-tumorigenic cell composition derived from **murine or human** embryonic stem cells,

the composition comprising **cells consisting essentially of at least about 66% isolated neural precursor cells and no more than about 34% isolated neural cells** ~~about 100% isolated neural cells and neural precursor cells~~, the neural precursor cells having the ability to differentiate into neuronal cells or glial cells, ~~and~~

wherein the cell composition is non-tumorigenic, **and**

**wherein the embryonic stem cells are not human genetically modified embryonic stem cells**.

48. (Previously Presented) The cell composition of claim 2, wherein the embryonic stem cells in (a) are cultured in serum-free medium.

49. (Cancelled)

50. (Previously Presented) The cell composition of claim 3, wherein the cell aggregates are embryoid bodies.

# DRAFT CLAIMS

51. (Cancelled)

52.-75. (Not entered)

76. (Currently Amended) A non-tumorigenic cell composition derived from **murine or human** embryonic stem cells, the composition comprising **cells consisting essentially of at least about 66% isolated neural precursor cells and no more than about 34% isolated neural cells**~~about 100% isolated neural cells and neural precursor cells that have~~ **the neural precursor cells having** the ability to differentiate into neuronal cells or glial cells, the composition being obtainable by:

(a) culturing the embryonic stem cells to produce neural precursor cells;

(b) culturing the neural precursor cells from (a) in a first growth factor-containing serum-free medium; and

(c) culturing the cells from (b) in a second growth factor-containing serum-free medium to produce neural spheres,

wherein the cells of the neural spheres are non-tumorigenic and comprise neural cells and neural precursor cells,

wherein the neural precursor cells have the ability to differentiate into neuronal cells, astrogilal cells, or oligodendroglial cells, **and**

**wherein the embryonic stem cells are not human genetically modified embryonic stem cells**.

77. (Previously Presented) The cell composition according to claim 76, wherein the embryonic stem cells in (a) are in the form of cell aggregates.

78. (Previously Presented) The cell composition of claim 77, wherein the cell aggregates are embryoid bodies.

# DRAFT CLAIMS

79. (Previously Presented) The cell composition of claim 76, wherein the embryonic stem cells in (a) are cultured in serum-free medium.

80. (Previously Presented) The cell composition according to claim 76, wherein the embryonic stem cells are obtained after nuclear transfer into oocytes.

81. (Previously Presented) The cell composition according to claim 76, wherein the embryonic stem cells are obtained from embryonic germ cells.

82. (Cancelled)

83. (Cancelled)

84. (Cancelled)

85. (Previously Presented) A cell library comprising cells according to claim 76, which are autologous and nonautologous cells.

86. (Previously Presented) A pharmaceutical composition comprising the precursor cells of claim 76.

87. (Cancelled)

88. (Previously Presented) The cell composition according to ~~claim 87~~**claim 106**, wherein the embryonic stem cells in step (a) are in the form of cell aggregates.

89. (Previously Presented) The cell composition of claim 88, wherein the cell aggregates are embryoid bodies.

90. (Previously Presented) The cell composition of ~~claim 87~~**claim 106**, wherein the embryonic stem cells in (a) are cultured in serum-free medium.

91. (Previously Presented) The cell composition according to ~~claim 87~~**claim 106**, wherein the embryonic stem cells are obtained after nuclear transfer into oocytes.

# DRAFT CLAIMS

92. (Previously Presented) The cell composition according to ~~claim 87~~**claim 106**, wherein the embryonic stem cells are obtained from embryonic germ cells.

93. (Cancelled)

94. (Cancelled)

95. (Cancelled)

96. (Previously Presented) A cell library comprising cells according to ~~claim 87~~**claim 106**, which are autologous and nonautologous cells.

97. (Previously Presented) A pharmaceutical composition comprising the precursor cells of ~~claim 87~~**claim 106**.

98. (Previously Presented) A cell library comprising cells according to claim 2, which are autologous and nonautologous cells.

99. (Previously Presented) A pharmaceutical composition comprising the precursor cells of claim 2.

100. (Previously Presented) The cell composition according to claim 2, wherein the second growth factor-containing serum-free medium comprises bFGF and EGF.

101. (Previously Presented) The cell composition according to claim 2, wherein the third growth factor-containing serum-free medium comprises bFGF and PDGF.

102. (Previously Presented) The cell composition according to claim 76, wherein the second growth factor-containing serum-free medium comprises bFGF and EGF.

103. (Previously Presented) The cell composition according to ~~claim 87~~**claim 106**, wherein the second growth factor-containing serum-free medium comprises bFGF and EGF.

# DRAFT CLAIMS

104. (Previously Presented) The cell composition according to ~~claim 87~~**claim 106**, wherein the third growth factor-containing serum-free medium comprises bFGF, EGF, or a combination thereof.

105. (Not entered)

106. (New) The non-tumorigenic cell composition of claim 47, wherein glial precursor cells are generated by:

(a) culturing the embryonic stem cells to produce the neural precursor cells;

(b) culturing the neural precursor cells from (a) in a first growth factor-containing serum-free medium;

(c) culturing the cells from (b) in a second growth factor-containing serum-free medium to produce neural spheres; and

(d) culturing the neural spheres from (c) in a third growth factor-containing serum-free medium to produce a monolayer of glial precursor cells,

wherein the glial precursor cells of the monoloayer are non-tumorigenic.